# **REMARKS**

# Phone Interview

Applicants would like to thank Examiner Seaman for her time spent on October 26, 2006 discussing the written description rejection over claim 8 and the introduction of a restriction requirement to separate out claim 8. During the phone interview, Examiner Seaman agreed to introduce a restriction requirement to remove the non-allowable claim (claim 8) into a separate invention in her response to our amendment. Accordingly, Applicants have not cancelled the non-allowable claim so that the Examiner could issue a formal written restriction requirement as discussed over the phone.

Applicants note that if the application is in condition for allowance, except for the cancellation of the non-allowable claim, Applicants request that the Examiner telephone the Applicants' agent to discuss cancellation of the non-allowable claim. Applicants are interested in working with the Examiner to place this application in condition for allowance.

### Status of the Claims

Claims 1 and 3-12 are currently pending in the present application. Claim 2 had previously been cancelled without prejudice or disclaimer of the subject matter claimed therein. New claims 11 and 12 have been added. New claims 11 and 12 are dependent from claims 9 and 10, respectively, and therefore are directed to the same invention as claims 9 and 10.

Claims 1, 3-7, 9 and 10 have been indicated in the last Office Action as allowable over the prior art of record.

# Amendments to the Specification

The specification has been amended to correct an inadvertent typographical error. As shown in formula (IIIb), " $R^xC(O)O$ " is an inadvertent typographical error since the substituent on "Ring A" is " $R^xOC(O)$ ."

### Amendments to the Claims

Claims 1, 3-6, 9 and 10 have been amended and new claims 11 and 12 have been added. The amendments to claims 1, 3-6, 9 and 10 and the addition of new claims do not introduce prohibited new matter.

Claim 1 has been amended to move the phrase "salt, solvate or pro-drug thereof" to the first line of the claims. Claims 3-6 have been amended to insert the phrase "salt, solvate or pro-drug thereof" for consistency in the claim format and for clarifying the claimed invention. Representative support for these amendments can be found in claim 1 as originally filed.

Claims 9 and 10 have been amended to correct an inadvertent typographical error by replacing "R<sup>X</sup>C(O)O-" with "R<sup>X</sup>OC(O)-" and to provide a value for R<sup>X</sup>. Representative support for these amendments can be found in the specification, for example, on page 16, in formula (IIIb) and in line 13.

Claims 1, 9, and 10 have also been amended to delete phrases that are not relevant in view of the previous amendments and to insert terms to clarify the claimed invention. Support for the amendments can be found in the claim as originally filed.

New claims 11 and 12 have been added. Representative support for these new claims can be found on page 16, lines 13 and 14.

# Rejection under 35 U.S.C. § 112, First Paragraph

A. Claim 8 has been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because the Examiner asserts that Applicants' specification allegedly does not adequately describe the nexus between the mediation through glucokinase and a useful treatment of a diabetes (type I and II as well as juvenile diabetes) and/or obesity.

Applicants respectfully point out that the specification describes the role that glucokinase plays in the metabolism of glucose. As discussed in the specification on page 1, glucokinase (GLK) phosphorylates glucose. It has been reported that the rate of glucose uptake is limited by the phosporylation of glucose or the activity of glucokinase and that Type 2 maturity onset diabetes is due to GLK loss of function of mutations, while hyperinsulinism is associated with activating GLK mutations (page 1, lines 10-33 of the specification). Moreover, it has been shown that intracerebroventricular (icv) infusion of glucose analogues that are competitive

inhibitors of glucokinase, stimulate food intake, while icv infusion of glucose suppresses feeding (page 2, lines 22-24). Accordingly, one would expect GLK activators to be useful for decreasing food intake and weight gain and in treating diabetes and obesity. Thus, the specification adequately describes the nexus between GLK activators and diabetes and obesity.

B. Claim 8 has been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

The specification discloses compounds known to activate GLK and describes in detail novel GLK activators of the present invention. The specification also discloses assays for determining whether novel activators are useful as activators of GLK activity (page 18 of the specification). Accordingly, one could use these assays to test whether a novel compound can be used as a GLK activator. Moreover, given that there are known GLK activators, one could compare the activity of a known GLK activator with that of a novel compound to assess the effectiveness of the novel compound as a GLK activator. Further, in the absence of evidence to the contrary, one would reasonably expect GLK activators determined to be effective by the disclosed assays, to be useful for treating diabetes and obesity based on the nexus between GLK activators and diabetes and obesity discussed above. Thus, the specification enables the claimed invention.

The Office Action alleges that the specification does not provide working examples, (factor 7 of the Wands factor). Applicants respectfully point out that MPEP 2164.02 states, "Compliance with the enablement requirement does not turn on whether an example is disclosed." Also, the court stated that an applicant need not have actually reduced the invention to practice prior to filing. *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987). Further, the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art would be able to practice it without undue experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). As discussed above, the subject application provides sufficient teaching throughout the specification to enable the skilled artisan to practice the invention without undue experimentation. Accordingly, Applicants request that this rejection be withdrawn.

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# Conclusion

Upon consideration of the foregoing, it will be recognized that Applicants have fully and appropriately responded to all of the Examiner's rejections. Accordingly, all claims are believed to be in proper form in all respects and a favorable action on the merits is respectfully requested. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

**Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

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